

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TRUSTEES OF THE UNIVERSITY OF
PENNSYLVANIA,

Plaintiff,

v.

ST. JUDE CHILDREN'S RESEARCH
HOSPITAL,

Defendant.

CIVIL ACTION

NO.

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Trustees of the University of Pennsylvania (the "University") brings this declaratory judgment action against defendant St. Jude Children's Research Hospital ("St. Jude"), and alleges the following:

PARTIES

1. The University is a non-profit organization devoted to higher education with a principal place of business at 3451 Walnut Street, Philadelphia, Pennsylvania 19104.
2. St. Jude is a non-profit pediatric cancer research hospital with a principal place of business at 262 Danny Thomas Place, Memphis, Tennessee 38105.
3. St. Jude is supported primarily by donations raised by its national fundraising organization, the American Lebanese Syrian Associated Charities ("ALSAC"), which was established expressly for the purpose of funding St. Jude.

JURISDICTION

4. This Court has original jurisdiction over the subject matter of this action pursuant to the provisions of Title 28, United States Code (“U.S.C.”) §§ 1331 (Federal Question), 1338(a) (Patents), 2201 & 2202 (Declaratory Relief). Jurisdiction also exists pursuant to § 1332(a).

5. Defendant St. Jude is subject to personal jurisdiction in this district because, *inter alia*, ALSAC, St. Jude’s charity, has both an office and a registered representative in the Eastern District of Pennsylvania.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

BACKGROUND

7. Carl H. June, M.D., a Professor of Pathology and Laboratory Medicine at the University’s Perelman School of Medicine, has developed a groundbreaking immunotherapy for treatment of cancer (the “Penn Immunotherapy”).

8. The Penn Immunotherapy involves use of a CD19 ScFv DNA lentiviral construct that, using proprietary technologies that Dr. June and his colleagues developed while at the University, causes T cells to express chimeric antigen receptors in patients such that their cancer is treated.

A. U.S. Patent No. 8,399,645.

9. Upon information and belief, St. Jude is the owner of U.S. Patent No. 8,399,645 which is entitled “Chimeric Receptors with 4-1BB Stimulatory Signaling Domain” and which issued on March 19, 2013 (“the ‘645 patent”). *See* Exh.A.

10. The ‘645 patent identifies Dario Campana and Chihaya Imai as the Inventors. *See id.*

11. The ‘645 patent states that “[t]his invention relates to chimeric cell membrane receptors, particularly chimeric T-cell receptors. This invention further relates to activation and expansion of cells

for therapeutic uses, in particular for activation and expansion of NK cells for chimeric receptor-based cell therapy.” *Id.*, col. 1, lns. 35-39.

12. The ‘645 patent states that “[i]n a most preferred embodiment of the invention the extracellular domain comprises a single chain variable domain of an anti-CD19 monoclonal antibody, the transmembrane domain comprises the hinge and transmembrane domain of CD8α, and the cytoplasmic domain comprises the signaling domain of CD3ζ and the signaling domain of 4-1BB.” *Id.*, col. 3, lns. 56-62.

13. The ‘645 patent also states:

Other aspects of the invention include polynucleotide sequences, vectors and host cells encoding a chimeric receptor that compromises the signaling domain of the 4-1BB. Yet other aspects include methods of enhancing T lymphocyte or natural killer (NK) cell activity in an individual and treating an individual suffering from cancer by introducing into the individual a T lymphocyte or NK cell comprising a chimeric receptor that comprises the signaling domain of 4-1BB. These aspects particularly include the treatment of lung cancer, melanoma, breast cancer, prostate cancer, colon cancer, renal cell carcinoma, ovarian cancer, neuroblastoma, rhabdomyosarcoma, leukemia and lymphoma. Preferred cancer targets for use with the present invention are cancers of B cell origin, particularly including acute lymphoblastic leukemia, B-cell chronic lymphocytic leukemia and B-cell non-Hodgkin’s lymphoma.

Id., col. 3, ln. 63 to col. 4, ln. 11.

14. The ‘645 patent also states:

Primary T cells expressing chimeric receptors specific for tumor or viral antigens have considerable therapeutic potential as immunotherapy reagents. Unfortunately, their clinical value is limited by their rapid loss of function and failure to expand *in vivo*, presumably due to the lack of co-stimulator molecules on tumor cells and the inherent limitations of signaling exclusively through the chimeric receptor.

The chimeric receptors of the present invention overcome this limitation wherein they have the capacity to provide both the primary effector activity and the co-stimulatory activity upon binding of the receptor to a single ligand. For instance, binding of the anti-CD19-BB-ζ receptor to the CD19 ligand provides not only the primary effector function, but also a proliferative and cytolytic effect.

T cells transduced with anti-CD19 chimeric receptors of the present invention which contain co-stimulatory molecules have remarkable anti-ALL capacity.

Id., col. 7, lns. 45-62.

B. Procedural Posture of Litigation Between the Parties

15. On July 11, 2012, St. Jude filed a complaint against the University in the United States District Court for the Western District of Tennessee (*St. Jude Children's Research Hospital, Inc. v. The Trustees of the University of Pennsylvania*, Civil Action No. 12-2579) ("the Tennessee Action") and alleged that the University breached two Materials Transfer Agreements ("MTAs") that related to the provision of biological material by St. Jude to the University and Dr. June.

16. The "Material" or "Materials" that are the subject of the MTAs are "biological material" provided by St. Jude to the University and Dr. June, and specifically, "the anti-CD19-BB- ζ chimeric T-cell receptor construct, including any progeny, portions, unmodified derivatives and any accompanying know-how or data." See 2003 and 2007 MTAs, attached hereto as Exhibits B and C, ¶ 1.

17. In its Complaint filed in the Tennessee Action, St. Jude states that "one of its researchers, Dr. Dario Campana, MD, Phd ("Dr. Campana) made the anti-CD19-BB ζ chimeric T-Cell receptor construct (referred to as the 'Receptor'). The Receptor is a molecule that can be put on the surface of a normal immune T-cell, causing it to recognize and attack B-cells that have the CD19 molecule on their surface." Complaint in Tennessee Action, attached hereto as Exhibit D ("St. Jude Complaint"), ¶¶ 17-18.

18. St. Jude equates the anti-CD19-BB ζ chimeric T-Cell receptor purportedly developed by Dr. Compana with the Materials transferred to the University under the terms of the MTAs. *See id.* ¶ 26.

19. In the Tennessee Action, St. Jude also alleges that the University had discussed the commercialization of the Materials, in violation of the MTAs. *See id.* ¶ 62.

20. In briefing related to the case, St. Jude has stated as follows:

The 2003 and 2007 MTAs were executed because Penn specifically sought to

obtain, and to collaborate with St. Jude on research involving, a biological material proprietary to St. Jude called a “chimeric antigen receptor” (“Receptor”). The Receptor is a molecule that enables a human immune cell to identify and attach a leukemic cancer cell. The Receptor was constructed entirely in a research laboratory at St. Jude in the early 2000s by Dr. Dario Campana and his staff, all of whom were St. Jude employees working at St. Jude in Memphis, Tennessee, where St. Jude’s only campus is located. In exchange for the Receptor, Penn agreed that legal title to the Receptor remained with St. Jude and voluntarily assumed strict obligations directed at protecting St. Jude’s proprietary and commercial interests in Tennessee: Penn agreed never to transfer the Receptor to anyone else, always to acknowledge the Receptor as St. Jude’s in publications, and never to commercialize the Receptor without St. Jude’s consent. However, Penn has breached the MTAs by hawking the Receptor as its own in recent scientific and other publications, and by commercializing the Receptor without St. Jude’s consent.

St. Jude Opp. to Defendant’s Motion to Dismiss, or in the Alternative, for a Change of Venue, attached hereto as Exhibit E, p. 1-2.

21. On July 19, 2012, the University filed a complaint against St. Jude in the United States District Court for the Eastern District of Pennsylvania (*The Trustees of the University of Pennsylvania v. St. Jude Children’s Research Hospital, Inc.*, Civil Action No. 12-4122) (“the Pennsylvania Action”), alleging that St. Jude tortiously interfered with the University’s prospective contractual relations and sought a declaratory judgment that the University had not breached the MTAs.

22. In its Complaint, the University states:

Carl H. June, M.D., a Professor of Pathology and Laboratory Medicine at Perelman, has developed a groundbreaking immunotherapy for treatment of cancer (the “Penn Immunotherapy”). The Penn Immunotherapy involves use of a CD19 ScFv DNA lentiviral construct (the “June Construct”) that, using proprietary technologies that Dr. June and his colleagues developed while at the University, causes T cells to express chimeric antigen receptors (“CARs”) in patients such that their cancer is treated. The strands of polynucleotide chains that make up DNA are held together by hydrogen bonds between complementary pairs of nitrogenous bases, or “base pairs.”

Complaint in the Pennsylvania Action, (“University Complaint”), attached hereto as Exhibit F, ¶ 8.

23. St. Jude moved to dismiss the University’s Complaint in the Pennsylvania Action. In its motion to dismiss, St. Jude stated:

In the early 2000s, one of St. Jude's researchers, Dario Campana, M.D., PhD developed a molecule—called a chimeric antigen receptor (“Receptor”)—which can be expressed on the surface of a normal human immune T-cell, and which causes the T-cell to recognize and attack certain leukemia cells. In December 2003, University researcher Dr. Carl June asked Dr. Campana to provide him with the Receptor and suggested a research collaboration involving use of the Receptor.

St. Jude Motion to Dismiss or Stay, attached hereto as Exhibit G, p. 3 (internal citations omitted).

24. St. Jude also alleges in its Motion to Dismiss that it “learned through a venture capitalist that the University was apparently engaging in prohibited commercialization efforts.” *See id.* p. 5.

25. St. Jude further alleges that on January 20, 2012, counsel for St. Jude informed University General Counsel that St. Jude was “prepared to sue the University immediately in order to preserve its interests.” *See id.*

26. In October 2012, the Tennessee Action was transferred to the United States District Court for the Eastern District of Pennsylvania and consolidated with the Pennsylvania Action. This consolidated proceeding is hereafter referred to as the “Consolidated Pennsylvania Action.”

27. The subject matter of the ‘645 patent directly relates to the same subject matter at issue in the Consolidated Pennsylvania Action.

28. The ‘645 patent concerns the use of chimeric cell membrane receptors, particularly chimeric T-cell receptors for therapeutic uses. *See Exh. A, Col. 1, lns. 35-39.*

29. St. Jude has already sued the University, claiming, *inter alia*, that it improperly commercialized St. Jude’s anti-CD19-BB ζ chimeric T-Cell receptor construct, known variously as the Receptor or the Materials. *See St. Jude Complaint, Exh. D, ¶ 81.*

30. Similarly, the University has already brought a declaratory judgment action to determine whether it breached the MTAs based on its use of the University’s CD19 ScFv DNA lentiviral construct, which causes T cells to express chimeric antigen receptors. *See The University Complaint, Exh. F, ¶ 69.*

31. St. Jude's statements and actions create a reasonable apprehension and belief on the part of the University that St. Jude will sue the University for infringement of the '645 patent.

32. Based on the foregoing, and in particular the relationship of the '645 patent to the subject matter of the Consolidated Pennsylvania Action, the University and St. Jude have adverse legal interests with respect to the '645 patent, and a substantial controversy exists between the University and St. Jude that is sufficiently immediate to warrant the issuance of a declaratory judgment.

33. By reason of the foregoing, a substantial and continuing controversy exists between the University and St. Jude regarding whether the University is liable for infringing the '645 patent. The University has instituted this Declaratory Judgment action for purposes of adjudicating that controversy.

COUNT I

Non-infringement of United States Patent No. 8,399,645

34. The University hereby incorporates by reference all previously stated allegations as if fully set forth herein.

35. The University has not infringed and is not infringing, either directly or indirectly, any valid and enforceable claim of the '645 patent.

36. The University seeks a judicial determination from this Court that it has not willfully or otherwise infringed and is not infringing, either directly or indirectly, any valid and enforceable claim of the '645 patent.

COUNT II

Invalidity of United States Patent No. 8,399,645

37. The University hereby incorporates by reference all previously stated allegations as if fully set forth herein.

38. The claims of the '645 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§

101, 102, 103, and/or 112.

39. The University seeks a judicial determination from this Court that the claims of the ‘645 patent are invalid.

RELIEF REQUESTED

WHEREFORE, the University requests that the Court enter a judgment in the University’s favor and against St. Jude, and provide the University with the following relief:

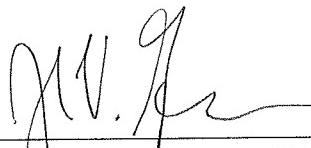
- Order, adjudge and decree that the University is not infringing any valid, enforceable claim of the ‘645 patent;
- Order, adjudge and decree that the ‘645 patent is invalid;
- Award such other and further relief as the Court may deem just and proper

DEMAND FOR JURY TRIAL

Plaintiff Trustees of the University of Pennsylvania hereby demand a trial by jury for each and every issue so permitted by law and statute.

Dated: March 22, 2013

Respectfully submitted,



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